

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q89732

SAHNI, Girish, et al.

Appln. No.: 09/940,235

Group Art Unit: 1652

Confirmation No.: 5356

Examiner: Sheridan Swope

Filed: August 27, 2001

For: NOVEL CLOT-SPECIFIC STREPTOKINASE PROTEINS POSSESSING ALTERED PLASMINOGEN ACTIVATION CHARACTERISTICS AND A PROCESS FOR THE PREPARATION OF SAID PROTEIN

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the personal interview conducted on November 8, 2005 between: Attorneys Mark L. Hayman and Chid Iyer of Sughrue Mion, Dr. Girish Sahni and Examiners Kerr, Swope and Proudly.

REMARKS

An Examiner's Interview Summary Record (PTO-413) was provided by Examiner Swope after the interview.

During the interview, the following was discussed.

1. **Brief description of exhibits or demonstration:** None.
2. **Identification of claims discussed:**

The following draft claim 34 was discussed:

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A chimeric polypeptide comprising the following components:

(a) a streptokinase component capable of plasminogen activation; and

(b) a fibrin-binding component, wherein said fibrin-binding component is fibrin-binding domains 4 and 5 of human fibronectin, or is fibrin-binding domains 1 and 2 of human fibronectin;

wherein said streptokinase component and said fibrin-binding component are fused via a peptide bond and are linked through a region that is sufficiently flexible so as to prevent activation of human plasminogen by said streptokinase, and so as to allow plasmin-dependent activation of said streptokinase component.

3. **Identification of art discussed:** Goldstein and Malke (of record).

4. **Brief Identification of principal arguments:**

Dr. Girish Sahni was prepared to discuss the non-obvious features of the peptide recited in draft claim 34, namely, initial inactivation of the peptide followed by plasmin-dependent activation.

Examiners Proudly, Kerr, and Swope asserted that these properties are irrelevant to the issue of obviousness because they are inherent in the molecule (see Examiner Interview Summary).

Applicants' attorneys noted that all properties of a molecule must be considered under section 103, especially those not taught or suggested by the prior art. (See MPEP §2141.02)

Despite these comments, the Examiners insisted that the properties of the molecule, which Dr. Sahni traveled from India to discuss with them, were not relevant to the issue of obviousness.

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Applicants' attorneys noted that Goldstein (which teaches an antibody-SK fusion) states, explicitly, that plasmin-dependent activation is "unexpected," was obtained by "serendipity," and was "not well understood." Applicants attorney asserted that, in view of Goldstein, the art does not allow one to reasonably expect to obtain these properties, or to engineer these properties, in a *different* SK fusion.

Examiners Proudly, Kerr, and Swope asserted that this disclosure of Goldstein is irrelevant because plasmin-dependent activation is an inherent property of the claimed peptide, and this is evident "in view of Applicants' disclosure."

Dr. Sahni further noted that, despite the Examiners misunderstanding of the law, the plasmin-dependent activation of the molecule is not inherent in the creation of a fusion with streptokinase. Dr. Sahni noted that Malke et al., which is of record in this application, teaches a fusion of SK with a different fibrin-binding peptide, and Malke does not report any such property.

Examiners Proudly, Kerr and Swope asserted that this was irrelevant because the plasmin-dependent activation was at least inherent in the chimeric peptide of draft claim 34.

Applicants' attorneys insisted that the Examiners misunderstood the law of obviousness.

Applicants' attorneys also wished to discuss the previous section 112, first paragraph rejection in the case, in which the Examiner asserted that the claims must be limited to specific sequences, because mutations in streptokinase and fibronectin may have unpredictable effects on the functions of the molecules.

It had been previously asserted by Applicants that limitation as to a precise sequence was unnecessary because streptokinase and fibronectin are well characterized in the art. Applicants

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had previously provided a wealth of prior art to establish this fact. It was believed that the Examiner had insufficiently addressed these remarks on the record.

Applicants' attorney noted the recent Federal Circuit case of *Capon v. Esshar v. Dudas*, which clarifies that a disclosure need not contain that which is in the prior art.

Dr. Girish Sahni was prepared to discuss prior art teaching crystal and solution structures of streptokinase and fibrin-binding domains of fibronectin, functional studies of these peptides and their functional domains, as well as many site-directed mutagenesis studies.

Although all of this information, much of which was already of record in the file, was communicated to Examiner Swope well before the personal interview so that she could familiarize herself with the issue and prior art of record, the Examiners were unprepared to discuss the issue and refused to listen to Dr. Sahni's explanation, despite the fact that he traveled from India for the interview.

5. **Identification of principal proposed amendments:** Briefly discussed claims limited to C-terminal fusions (SK-FBD) or fusions on both ends of SK. The Examiners expressed little view.

6. **Indication of other pertinent matters discussed:** None.

7. **Results of Interview:** No agreement was reached.

Applicants were disappointed with the Examiners preparedness, understanding of the relevant law, and willingness to listen.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

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It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

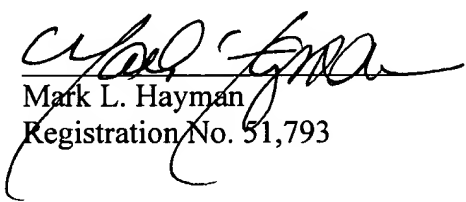
Respectfully submitted,

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Date: November 9, 2005.